



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-D-0239]

Assessing the Center of Drug Evaluation and Research's Safety-Related Regulatory Science Needs and Identifying Priorities; Report; Availability; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a report entitled "Assessing CDER's Drug Safety-Related Regulatory Science Needs and Identifying Priorities." This report identifies drug safety-related regulatory science needs and priorities related to the mission of FDA's Center for Drug Evaluation and Research (CDER) that would benefit from external collaborations and resources. FDA hopes to foster collaborations with external partners and stakeholders to help address these needs and priorities. This notice asks stakeholders conducting research related to these needs to describe that research and indicate their interest in collaborating with FDA to address safety-related research priorities.

DATES: Although you can comment on the report at any time, to ensure that FDA considers your comments on this report, submit either electronic or written comments on the report by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit written requests for single copies of this report to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993. Send one self-addressed adhesive label to assist that office in processing your requests. See the SUPPLEMENTARY INFORMATION section for electronic access to the report.

Submit electronic comments on the report to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ruth Barratt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 21, rm. 4540, Silver Spring, MD 20993-0002, 301-796-2600.

SUPPLEMENTARY INFORMATION:

I. Background

Since publication of the 2011 “Identifying CDER’s Science and Research Needs” report, FDA has been engaged in efforts to further assess and prioritize the needs articulated therein. As part of these efforts, CDER’s Safety Research Interest Group (SRIG), a subcommittee of the Science Prioritization and Review Committee, assessed CDER’s overall drug safety-related regulatory science needs in view of FDA’s ongoing research efforts and highlighted areas that would benefit from additional resources and collaboration.

The SRIG identified the following seven overall needs for drug safety-related regulatory science:

1. Improve access to postmarket data sources and explore the feasibility of their use in safety signal analyses

2. Improve risk assessment and management strategies to reinforce the safe use of drugs
3. Evaluate the effectiveness of risk communications of drug safety information to health care providers and the public
4. Improve product quality and design, manufacturing processes, and product performance relating to safety
5. Develop and improve predictive models of safety in humans, including nonclinical biomarkers
6. Improve clinical trial statistical analyses for safety, including benefit-risk assessment
7. Investigate clinical biomarkers of safety, including standards for qualification.

Particular priorities within the seven overall needs requiring further resources and outside participation were also identified. FDA seeks to stimulate collaborations with external partners and stakeholders to address these needs by asking them to: (1) Submit descriptions of their ongoing research and initiatives related to the seven overall needs, especially the identified priorities, and (2) indicate their interest in working with FDA to address these needs. Outside parties are being asked to submit comments to the docket and email address

CDER_Science_Needs@fda.hhs.gov.

II. Comments

Interested persons may submit either electronic comments regarding the report to <http://www.regulations.gov> and email address CDER_Science_Needs@fda.hhs.gov, or written comments to the Division of Dockets Management (see ADDRESSES). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets

Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the report at <http://www.regulations.gov>.

Dated: March 13, 2015.

Leslie Kux,

Associate Commissioner for Policy.

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